



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 11, 2018

Lizette Bonvin  
Principal Regulatory Specialist  
Diversey, Inc.  
P.O. Box 19747  
Charlotte, NC 28219

Subject: Label Amendment – Adding the Emerging Pathogens Claims  
Product Name: Oxivir Wipes  
EPA Registration Number: 70627-60  
Application Date: 12/23/2017  
Decision Number: 537379

Dear Ms. Bonvin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at [heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov).

Sincerely,

A handwritten signature in blue ink, appearing to be 'ZB', with a long horizontal stroke extending to the right.

Zeno Bain, Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Stamped Label

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer. Changes from previous approved label are highlighted in yellow.)

## OXIVIR™ WIPES

(Ready to Use) (Easy to Use) (Towelette) (Wipe)  
(One-Step Disinfectant and Deodorizing Wipes)

- (Sanitizer) •(Sanitizing Wipes) •(Cleaner) •(Disinfectant) •(Deodorizer)
- (Virucidal) •(Bactericidal) •(Fungicidal) •(Tuberculocidal)
- (Meets OSHA Bloodborne Pathogen Standards)
- (Kills Norovirus)

(Use on non-food contact surfaces, including: (Grocery Cart Handles) (Cash Registers)  
(Telephones) (Doorknobs))

- (Just pull, wipe, let wet surfaces sit for 1 minute & toss!) •(Eliminates Buckets) •(No need to Spray!)
- (Pre-moistened) •(Pre-measured) • (Always Ready-to-Use)
- (No measuring or mixing required)

(Hydrogen Peroxide)

(For (Hospital) (Health Care) (Industrial) (&) (Institutional) (and) (Residential) Use)

**ACCEPTED**

Jun 11, 2018

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 70627-60

### ACTIVE INGREDIENT:

Hydrogen Peroxide..... 0.5%

**OTHER INGREDIENTS:** ..... 99.5%

**TOTAL:**..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**Emergency Number: XXX-XXX-XXXX**

Net Contents: xxxxxxxxxxxxxxxx

EPA Reg. No. 70627-60

EPA Est. No. xxxxxxxxxxxxxxxx

(Lot code letters indicate establishment number.)

[Made in (Product of) xxxxxxxxxxxxxxxx]

[Manufactured][Distributed][by][for]: © 2017 Diversey, Inc., P.O. Box 19747, Charlotte, NC 28219-0747 USA

(See reference sheet (enclosed in each case) for (a completed list of organisms) (additional (features) (claims)  
(directions for use)) (for this product)).

**(CLAIMS:** *These may be used partially, in their entirety, or may be combined appropriately with commas, changes in capitalization, and addition of “and” as necessary, or not at all.*)

**(MARKETING CLAIMS):**

*(General)*

A disinfectant cloth for use on telephone surfaces and other telecommunications equipment surfaces  
A Hydrogen Peroxide solution impregnated in a wiping cloth  
Aids in reducing (or in the reduction of) cross contamination between treated surfaces  
Always ready to use  
An effective way to clean, deodorize against odor-causing organisms and disinfect hard, non-porous surfaces  
An effective way to disinfect hard, non-porous environmental surfaces  
Built-in Scrubbing Fibers  
Clean & disinfect any room, any time  
Clean & disinfect hard non-porous surfaces  
Clean & disinfect hard non-porous surfaces easily  
Cleaner and disinfectant towel (or cloth)  
Cleans and disinfects  
Cleans and disinfects (cell phone surfaces) (telephone equipment) (telephone equipment surfaces) (dictating equipment surfaces) (telecommunications equipment surfaces) (devices)  
Cleans and disinfects common hard, non-porous surfaces  
Cleans, deodorizes and disinfects  
Cleans, deodorizes and brightens in one step  
A (cleaner) (and) (disinfectant (and) cleaner (that (cleans), (disinfects) and (deodorizes) in one labor saving step)  
Cloth  
Chlorine free (No (chlorine) (bleach))  
Compatible with most hard, nonporous surfaces  
Contains no (abrasives) (bleach) (or) (harsh acids)  
Contains no phosphates  
Compatible with (Suitable for) (Will not harm) most hard non-porous surfaces. (No bleach (or chlorine) stains)  
Deodorizer (Odor Counteractant) (Odor Neutralizer)  
Convenient  
Convenient & easy cleaning all around (the office) (business) (workplace)  
Cuts grease  
Cuts the toughest grime and grease without scratching surfaces  
Disposable  
Pre-moistened towelettes (disposable wipes) clean, deodorize and kill listed bacteria all around your (office) (business) (workplace)  
Easy to use – just wipe, (and) let wet surfaces sit for 1 minute (and) (walk away).  
Easy / Effective  
For everyday use (in (institutional) (and) (industrial) facilities)  
For hard, non-porous surfaces  
For use in critical care areas (where control of the hazards of cross-contamination between treated surfaces is of prime importance)  
For use (in) (Hospitals), (Health Care) (settings) (as a multi-purpose disinfectant cleaner)  
For your toughest bathroom messes  
Formulated with patented hydrogen peroxide technology

Formulated with patented AHP technology  
(Fragrance Free) (Unscented) Formula  
Great on-the-go disinfectant (cloth)  
Hard non-porous surface (cleaning &) disinfecting made easy Heavy-duty cleaner (or cleaning) (cloth)  
Help make your (the) [*insert any use site from use site section*] Oxivir Clean  
Just pull, wipe, let wet surfaces sit for 1 minute and toss!  
No fragrance added (No added fragrance)  
No rinse required  
Non-corrosive (to eyes) (and) (skin)  
Non-tainting (leaves no unsightly residues)  
Non-woven disposable cloth  
Not a skin (dermal) sensitizer (non-sensitizer)  
Pre-measured (towelette) (towelettes) (wipe) (wipes)  
Pre-moistened (towelette) (towelettes) (wipe) (wipes)  
Pre-soaked (cloth or towelette or wipe)  
Efficiently (eliminates) (removes) (bad) (mal)odors  
Quaternary ammonium compound-free (No quaternary ammonium compounds)  
Restroom Wipes for hard, non-porous surfaces  
Stay-moist package  
(Step-saving), (Labor-saving), (Time-saving), (Cost-saving) formula  
Strong towelettes (or wipes)  
Suitable for everyday use  
Towel  
Use on hard, non-porous surfaces only. (Test wipe on a small inconspicuous area first)  
Use to disinfect shopping (or grocery) cart handles  
Wipe down grocery (or shopping) cart handles

*(Cleaning)*

An effective counter cleaner  
Built-in scrubbing fibers  
Cleans without scratching surface(s)  
Cleaner  
Clean(s) and deodorize(s)  
Cleans effectively  
Cleans hard-to-remove stains  
Clean you expect  
Cleans fast  
Cleans sealed grout  
Cleans hard, non-porous water washable surfaces!  
Cleans (removes) (eliminates) (destroys) stains  
Cleans (tough) grease and grime (and) (institutional) (soils) (fast)  
Cleans (tough) soap scum  
Cleans without bleaching  
Compatible with (equipment) and (hard) (non-porous) surfaces  
Convenient, (effective) (efficient) (&) easy cleaning  
Effective daily cleaner  
Effective against soap scum  
For a cleaner, fresher [*insert any use site from use site section*]  
For multiple cleaning tasks

For non-scratch cleaning of showers and tubs, shower doors and (nonporous) curtains, fixtures and toilet bowls

Good for most indoor cleaning tasks

Grease Cutting Formula

Great for grease cutting

Great for on-the-go cleaning

Intense cleaning action

Keeps day care centers clean

Leaves no (dull) (sticky) residue

Leaves (office) (washroom) (restroom) (bathroom) smelling clean

Leaves surfaces virtually streak-free

No mixing

No streaking

Powerful clean

Powers away tough stains (stuck on dirt)

(Efficient) (effective) (and) easy cleaning everywhere

Removes tough stains

Scrubbing surface cleaner

(Specially) (Specifically) designed to dissolve (penetrate) the toughest (stubborn) soils

Use daily to prevent the build-up of dirt and grime

Uses (Harnesses) the cleaning power of hydrogen peroxide

Will not leave grit or soap scum

**(Antimicrobial-related statements)**

Antimicrobial

Antimicrobial (surface) Cleaner (cloth)

Antimicrobial Cell phone Wipe

Anti-microbial cleaner (cloth)

Bactericidal Cleaner

Bactericidal

Bactericidal (surface) Cleaner (cloth)

Bactericidal Cell phone Wipe

\*Virucidal

\*Virucidal (Surface) Cleaner (cloth)

\*Virucidal Cell phone Wipe

Broad-Spectrum (Multi-Purpose) (Multi-Surface) (Bactericidal) (\*Virucidal) (Tuberculocidal) (Fungicidal) (Sanitizer) (Disinfectant) (Activity) (Cleaner)

Controls the spread of listed bacteria on treated hard, non-porous environmental surfaces

Controls (Eliminates) odor-causing bacteria

Disinfects as it cleans

(Disinfects) (Kills germs) for a deep-down clean

Disinfectant (disinfecting) surface cleaner (cloth) (wipe)

Disinfects against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*

Disinfects environmental surfaces

Disinfects hard, non-porous environmental surfaces

Disinfects headsets and telephones

Dual action formulation providing broad spectrum activity against; fungi, mycobacteria, \*viruses, and bacteria

Each pre-moistened towelette (disposable) (wipe) cleans and deodorizes all around the [*insert any use site from use site section*].

Pre-moistened towelette (disposable) (wipe) cleans, deodorizes and kills listed bacteria all around the [*insert any use site from use site section*]. Just wipe and let surface remain wet for 1 minute.

Effective against flu virus (Influenza A/Hong Kong)

Effective in 1 minute against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*

Effectively disinfects hard, non-porous surfaces

Effectively disinfects in the presence of organic soil (5% blood serum)

Everyday, every room disinfectant

Exhibits effective virucidal activity: kills Influenza A/Hong Kong and Herpes Simplex Type 2

Kills antibiotic resistant organisms<sup>†</sup> [*list of antibiotic resistant organisms is below, in Efficacy Claims section, under subheading Antibiotic-Resistant (Strains of) Bacteria*]

Kills bacteria (and sanitizes)

Kills bacteria (and viruses) (on hard, non-porous surfaces) in 1 minute

Kills (Destroys) (Eliminates) germs while it cleans

Kills (Effective against) cold virus on hard, non-porous surfaces

Kills (Effective against) flu virus on hard, non-porous surfaces

Kills (Effective against) cold and flu virus on hard, non-porous surfaces

Kills odor-causing bacteria

Kills viruses (in 30 seconds)

Kills (99.9% of) germs (in 1 minute)

Kills (99.9% of) (cold) (and) (flu) (viruses) in 30 seconds

Kills Avian Influenza A virus on pre-cleaned environmental surfaces

Kills: *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*

Kills the flu virus Influenza A

Kills Norovirus (Norwalk virus)

Kills Human Coronavirus

Kills HIV-1 (AIDS virus) (HTLV-III<sub>B</sub>)

Kills HCV

Kills HBV

On-the-go disinfectant

Oxivir™ (Tb) Wipes control the spread of listed bacteria on treated hard, non-porous environmental surfaces

Oxivir™ (Tb) Wipes help control listed bacteria on treated surfaces while keeping your office (or workstation or workplace or business) clean and dust-free

Restroom Disinfectant Wipes

Telephone (cleaner [and] disinfectant) wipes

These wipes are a convenient way to disinfect surfaces all around your (business) (office) (workplace)

Versatile (convenient) (disinfectant) (or disinfecting) cleaner

\*Virucidal (or) Kills viruses Influenza A/Hong Kong (Hong Kong flu), Herpes Simplex Type 2, HCV, HBV, HIV-1

Virus killing cleaner

### **(New & Improved Claims)**

{*Note to reviewer: New and approved claims only to be used for maximum 6 months, and in accordance with New and Approved claims guidance*}

New (packaging) (!)

New & Improved (Packaging) (!)

Improved (Cleaning) (Scrubbing)



**(Packaging Claims)**

Assures proper dilution strength for product effectiveness  
Easy flip-top lid  
(Eliminates buckets)  
Dispenses exactly what you need  
Take (1) (one) or Many Wipes  
Easy to Dispense  
Hassle Free Lid  
Never fight the lid again  
Unique lid design  
No need to remove lid to get to wipes  
No more pinched fingers  
No more broken lids  
Stronger Wipes!  
One handed dispensing  
Great for on the go  
Mounts to (on) virtually anything (any surface)  
Portable & Accessible Design  
Wipes where and when you need them  
Less packaging than traditional bucket  
Uses (10 or 15 or 20 or 25)% less (packaging) (plastic) [than (traditional) (standard) (canister) (wipes) (packaging)] [*Note to reviewer: only one number will be used on final label, depending on which package is used*]  
Helps to support your (sustainability) (Corporate Social Responsibility) (CSR) (reduced packaging) (reduced packaging waste) initiatives  
Takes up less space  
Portable  
Easy to dispense  
Made with less plastic  
Reduced packaging material  
Made with the environment in mind  
One handed dispensing  
Ideal for daily cleaning and disinfecting  
Dispensing Simplified  
Wipes Simplified  
Easy carry handles  
Secure bracket  
Just insert in dispenser (bracket) for one handed dispensing  
Now (10 or 15 or 20 or 30 or 40)% stronger package [*Note to reviewer: only one number will be used on final label, depending on which substrate and/or package is used*]  
Now (10 or 15 or 20 or 30 or 40)% stronger wipe [*Note to reviewer: only one number will be used on final label, depending on which substrate and/or package is used*]  
Now (10 or 15 or 20 or 30 or 40)% stronger towelette [*Note to reviewer: only one number will be used on final label, depending on which substrate and/or package is used*]  
No more wasted wipes  
Portable or can be attached to brackets  
Point of care dispensing or access or availability  
No threading



Our (best or easiest or fastest) dispensing ever(!)  
Just pull and go  
Pull up for many pull forward for one wipe(s)  
Wipes on demand  
Easy to use (dispenser) (package)  
Easy (to store) (to start dispensing) (to use lid)  
Stackable packs  
(Stays) (keeps) wipes wet  
Convenient  
Versatile packaging for every need  
Ready to dispense  
(Regular or Clinical or Large or EVS) Wipe size  
Snap and seal closure  
Same great product, (easier or better or improved) package  
Wipes that clean better  
Wipes are stronger  
Wipes can do more  
Clean Better  
Clean and disinfect more easily  
Travel size  
Great for on the go disinfection  
Convenient package size great for on the go  
Puts wipes where you need them  
Puts wipes always within reach  
Clean and disinfect when the moment strikes  
Clean and disinfect when the occasion strikes  
Clean and disinfect key moments  
Increase moments of disinfection  
Just pop the top and grab a wipe  
Place container where you need it  
Wipes always when and where you need them  
Quick lock wipe dispenser  
First time use, lift here  
First time use, do not remove lid  
First time use, lift here to expose seal  
Not a baby wipe  
Wipe dispensing simplified  
Stronger Wipes  
Wipes when and where you need them  
Large wipes perfect for everyday disinfection  
Powered by AHP  
Just flip the lid and grab a wipe  
Stand-up pouch takes up less space than bulky buckets  
Easy dispensing, happy (nurses, staff, employees, users)  
*Do Not Remove Lid*  
*Open Lid Here*  
*Tear/Break/Puncture film to expose wipe roll*  
*Remove seal for first wipe*

*Remove seal for wipe access*

*Tear Here*

*Remove seal here*

*Pull Seal Here*

*Remove to access wipe roll*

**(Additional Claims)**

(Oxivir Tb Wipes) (This product) (These) (are) (is a) non-woven, disposable (towelette(s)) (wipe(s)), pre-saturated with Hydrogen Peroxide (based) disinfectant cleaner.

(Oxivir Tb Wipes) (This product) is a one-step (hospital-use) germicidal (disinfectant) cleaner and deodorant (odor-counteractant) (odor neutralizer) (towelette) designed for general cleaning, (and) disinfecting, (and) (deodorizing) (of) hard, non-porous environmental surfaces.

(Oxivir Tb Wipes') (This product's) (Its) (non-dulling) (advanced) (cleaning) (convenient) (easy-to-use) (effective) formula eliminates the time and labor normally required for rinsing.

(Oxivir Tb Wipes') (This product's) (Its) (non-dulling) (advanced) (cleaning) (convenient) (easy-to-use) (effective) formula is designed for use on (Use daily on) (Use daily to clean and disinfect) (*insert use sites/surfaces from lists below*)

(Oxivir Tb Wipes') (This product's) (Its) non-abrasive formula is designed for use on (Use daily on) (the following) [*insert use sites/surfaces from lists below*]

(Oxivir Tb Wipes') (This product's) (Its) non-abrasive formula is designed for use on (Use daily on) hard, non-porous environmental surfaces.

(Oxivir Tb Wipes) (This product) (It) cleans by removing dirt, grime, dead skin, blood, urine, fecal matter, body oils and other (organic matter) (common soils) found in [*insert use sites/surfaces from lists below*] (or – any hard, non-porous washable surface where disinfection is required.)

(Oxivir Tb Wipes) (This product) (It) also eliminates odors, leaving (restroom) surfaces smelling clean and fresh. Use where odors are a problem.

(Oxivir Tb Wipes) (This product) cleans, disinfects and deodorizes hard, non-porous environmental (hospital) (medical) (dental) (laboratory) [*insert use sites/surfaces from lists below*] surfaces in one step (with no rinsing required).

(Oxivir Tb Wipes) (This product) cleans, disinfects and deodorizes surfaces by killing odor-causing microorganisms. Its (non-dulling) (advanced) (efficient cleaning) (convenient) (easy-to-use) (effective) formula is designed for use on (Use it daily) on) [*insert use sites/surfaces from lists below*]

(Oxivir Tb Wipes) (This product) (It) (is designed for use on) (Use daily on) (the following) (hard, non-porous environmental (inanimate) surfaces): (*insert use sites/surfaces from lists below*) or – any hard, non-porous washable surface where disinfection is required.

Do not use on glasses, dishes and utensils.

Not recommended for use on brass, copper or marble.

(Oxivir Tb Wipes) (This product) has been developed to aid in the reduction of cross-contamination between treated surfaces (not only in hospitals (and healthcare facilities), but also) in:) [*insert use sites/surfaces from lists below*]

Note: Prior to use on electronic equipment or components, (please) refer to manufacturer's instructions (for appropriate use).

## **(USE SITES:)**

[(Oxivir Tb Wipes) (This product) can be used (in) (on) the following hard non-porous (areas) (surfaces):]

### **(Medical Facilities/Hospitals/Health Care Facilities/Dental Offices/Life Science Laboratories :)**

- alternative care facilities,
- ambulances or (emergency medical) transport vehicles,
- ambulatory care centers (ASCs); ambulatory surgery centers,
- anesthesia rooms,
- assisted living facilities,
- (acute) (and) (long-term) care facilities,
- backboards,
- (hospital) (patient) bedrails and linings (patient bed linings), (vinyl mattress covers),
- bedpans,
- (hospital) (patient) bedrails, bedframes, bed springs, side rails,
- bedside (overbed) table,
- (bedside) commodes,
- blood pressure cuffs (for use on hard, non-porous surfaces)
- blood pressure monitors,
- CAT laboratories,
- (crash) (medication) carts,
- cabinets,
- (nurse) call buttons (boxes) (devices),
- (central service areas,
- central supply rooms,
- clinics,
- critical care units,
- dental chairs,
- dental clinics,
- dental curing lights,
- dental offices,
- dental operatory surfaces,
- diagnostic equipment,
- dialysis clinics (facilities),
- (blood) (plasma) donation centers,
- examination (exam) rooms (areas),
- exam tables
- emergency rooms (ERs) (areas),
- eye surgical centers,
- footboards,
- gurneys,
- health care facilities,
- high-touch surfaces,
- home health care (settings),
- hospices,
- hospitals,
- infant incubators,
- instrument trays,
- IV stands (poles) and exterior surfaces of pumps,
- (medical) (neonatal) (pediatric) (surgical) intensive care units (ICUs) (MICUs) (NICUs) (PICUs) (SICUs) (areas),
- isolation rooms (areas),
- laboratories,
- laboratory settings
- laundry rooms,
- long-term care facilities (homes),
- (medical assistance services),
- medical facilities,
- (medical) (physicians') (doctors') offices,
- (neonatal) (newborn) nurseries,
- non-critical medical equipment surfaces,
- nursing homes,
- nurses stations,
- operating rooms (theaters),
- ophthalmic offices,
- outpatient (surgical) centers (clinics) (OPSCs) (facilities),
- paddles,
- patient rooms (areas),
- patient care (monitoring) equipment,
- pharmacies,
- phlebotomy trays,
- (physical) (patient) therapy rooms,
- physical therapy equipment,
- procedure rooms,
- psychiatric facilities,
- radiology (X-Ray) rooms (areas),
- reception areas,
- recovery rooms,
- rehabilitation centers,
- respiratory therapy rooms,
- skilled nursing facilities,
- stethoscopes,
- stretchers,
- surgery rooms,
- traction bars, devices and patient slings,
- waiting rooms (areas)
- wash basins,
- wheelchairs,
- x-ray equipment,

**(USE SITES, continued)**

[(Oxivir Tb Wipes) (This product) can be used (in) (on) the following hard non-porous (areas) (surfaces):]

**(Animal/Veterinary Facilities/Animal Housing Facilities:)**

- airports,
- animal equipment,
- animal crates,
- animal hospitals,
- animal housing facilities,
- animal treatment facilities,
- animal life science laboratories,
- automatic feeders (not for food contact),
- barns, pens, and stalls,
- bathrooms,
- brushes,
- buckets,
- bus (depots) (stations),
- cages,
- carts,
- counters,
- crates,
- dog runs,
- examination tables
- exercise facilities,
- exercise equipment,
- farm vehicles (trucks),
- fencing,
- fume hoods and animal cages (found in laboratory settings),
- farms,
- gates,
- gathering (guiding) equipment,
- general merchandise stores,
- grooming equipment,
- grooming facilities,
- health clubs,
- handling equipment,
- harnesses & leashes,
- kennels,
- kennel runs,
- laboratories or other small animal facilities,
- office buildings,
- pens,
- pet shops (equine farms),
- shower rooms (areas),
- troughs,
- veterinary clinics
- veterinary equipment,
- veterinary care surfaces,
- (wash) stalls,

**(General Areas:)**

- airports,
- aluminum
- athletic equipment,
- athletic facilities,
- baked enamel surfaces associated with floors,
- barber/beauty (salons) (shops),
- exterior surfaces of air vents covers,
- cabinets,
- cages,
- carts,
- casinos,
- ceilings
- chairs,
- changing tables,
- chrome
- closets,
- coated (removable) (plastic) covers for mattresses and pillows,
- computer mouse, keyboards, peripherals, screens, tables,
- convenience stores,
- convention centers,
- correctional facilities,
- counters (not for food contact),
- cruise ships,
- day care centers,
- desks,
- desktops,
- docking stations,
- doors,
- drawers,
- elevators,
- exercise equipment,
- exercise facilities,
- faucets,
- fixtures,
- floors (flooring),
- funeral homes,
- glass,
- glazed ceramic,
- glazed ceramic (restroom) tile,
- glazed porcelain,
- glazed tile,
- handheld electronic devices,
- handles,
- hand rails (railings),
- high touch non-food contact surfaces,
- homes cleaned by (home cleaning services) (professional cleaning services),
- hotels (motels),
- institutions,
- laminated surfaces
- laptops,
- laundromats,
- libraries,
- light fixtures, switches,
- lockers,
- locker rooms (areas),
- lounges,
- mirrors,
- military installations,
- mobile devices (electronic equipment),
- mobile workstations,
- Naugahyde,

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer. Changes from previous approved label are highlighted in yellow.)

- non-food contact countertops,
- non-food contact surfaces,
- office buildings
- pagers,
- painted surfaces,
- phones, phone cradles and accessories,
- plastic (surfaces),
- plated steel
- playgrounds,
- public areas,
- public buildings,
- public restrooms,
- recreational facilities,
- restrooms,
- rest stops (public restrooms),
- retail businesses,
- schools (colleges, and universities),
- shelves,
- shopping centers,
- showers,
- shower fixtures,
- shower rooms (areas)
- sinks,
- sink basins,
- sinks found in (health care facilities),
- (hospitals), (dental offices), (patient rooms), (operating rooms), (ICU areas), (shower rooms), and (locker rooms)
- stainless steel,
- stools,
- spas,
- sports arenas (stadiums)
- train (depots) (stations),
- transportation terminals (facilities),
- tables,
- tablet PCs,
- telephones,
- tubs,
- exterior surfaces of toilets,
- toilet exteriors,
- toilets
- exterior surfaces of urinals,
- urinal exteriors,
- urinals,
- walls,
- wash basins,
- vinyl,

#### **(EFFICACY CLAIMS:)**

(When used as directed, (Oxivir Tb Wipes) (This product) is effective against a wide variety (broad-spectrum) of pathogenic microorganisms (including bacteria, tuberculosis, antibiotic resistant bacteria [*list of antibiotic resistant organisms is below, in Efficacy Claims section, under subheading Antibiotic-Resistant (Strains of) Bacteria*], viruses, and fungi.) (See reference sheet (enclosed in each case) for a complete list of organisms).

#### **HOSPITAL DISINFECTANT:**

**BACTERICIDAL** in the presence of 5% serum load and 1 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

#### **Bactericidal Activity:**

*Staphylococcus aureus*, (ATCC 6538)

*Pseudomonas aeruginosa*, (ATCC 15442)

*Salmonella enterica*, (ATCC 10708), formerly known as *Salmonella choleraesuis*

*Acinetobacter baumannii*, (ATCC 19606)

*Escherichia coli* O157:H7, (ATCC 35150)

*Escherichia coli* with extended beta-lactamase resistance (ESBL), (ATCC BAA-196)

*Klebsiella pneumoniae*, (ATCC 4352)

*Shigella dysenteriae*, (ATCC 11835)

#### **†Antibiotic-Resistant (Strains of) Bacteria [*list below*]:**

*Enterococcus faecalis*, (ATCC 51575)

*Staphylococcus aureus* (CA-MRSA), (Resistant to Vancomycin (VRE))

(NARSA NRS 384)(Genotype USA300) Community Associated Methicillin Resistant

*Staphylococcus aureus*, (ATCC 33592)

*Staphylococcus aureus* (CA-MRSA), (Resistant to Methicillin (MRSA))

(NARSA NRS 123)(Genotype USA400) Community Associated Methicillin Resistant

**\*VIRUCIDAL** in the presence of 5% serum load and 1 minute contact time at 20°C (68° F) on hard, non-porous environmental surfaces.

#### **Viruses (Virucidal Activity):**

Adenovirus type 8, (ATCC VR-1368)

Herpes Simplex Virus, Type 2 (HSV-2), (ATCC VR-734)

HIV-1 (AIDS Virus), Strain HTLV-III<sub>B</sub> (HIV-1), (Acquired from Adv. Biotechnologies, Inc.)

Human Coronavirus, (ATCC VR-740)

Norovirus, (Feline Calicivirus, ATCC VR-782 as the surrogate)

Poliovirus Type 1, Strain Brunhilde, (ATCC VR-1000)

Rhinovirus Type 14, (ATCC VR-284)

Hepatitis B Virus (HBV), (Acquired from Hepadnavirus Testing)

Hepatitis C Virus (HCV), (Acquired from National Veterinary Services Laboratories)

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer. Changes from previous approved label are highlighted in yellow.)

Herpes Simplex Virus, Type 1 (HSV-1), (ATCC VR-733)

Influenza A/Hong Kong, (ATCC VR-544)

Rotavirus WA, (Acquired from University of Ottawa)

#### **(Veterinary Viruses:)**

Avian Influenza A (H3N2), (ATCC VR-2072)

Feline Calicivirus, Strain F9, (ATCC VR-782)

**TUBERCULOCIDAL** in the presence of a 5% serum load and 5 minute contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

*Mycobacterium bovis* (Tb) (OT 451C150)

**FUNGICIDAL** This product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (ATCC 9533) (the fungus which causes Athlete's Foot) in the presence of a 5% serum load and 10 minute contact time at 20°C (68°F) when used as directed on hard, non-porous surfaces found in bathrooms, shower stalls, locker rooms, or other clean, hard, non-porous, surfaces commonly contacted by bare feet.

*Trichophyton mentagrophytes* (ATCC 9533)

**Non-Food Contact Surface Sanitizer for hard non-porous surfaces** in the presence of a 5% serum load and 30 second contact time (at 20°C (68°F)) on hard, non-porous environmental surfaces.

*Enterococcus faecalis*, (ATCC 51575)

*Pseudomonas aeruginosa*, (ATCC 15442)

*Staphylococcus aureus*, (ATCC 6538)

(Resistant to Vancomycin [VRE])

*Escherichia coli* O157:H7, (ATCC 35150)

*Salmonella enterica*, (ATCC 10708)

*Staphylococcus aureus*, (ATCC 33592)

(Resistant to Methicillin [MRSA])

*Klebsiella pneumoniae*, (ATCC 4352)

**Non-Food Contact Surface Sanitizer for hard non-porous surfaces** – in the presence of a 5% serum load and 30 second contact time at 20°C (68°F) on hard, non-porous environmental surfaces.

*Klebsiella pneumoniae* (ATCC 4352)

*Salmonella enterica*, (ATCC 10708)

*Pseudomonas aeruginosa* (ATCC 15442)

*Staphylococcus aureus* (ATCC 6538)

(formerly known as *Salmonella choleraesuis*)

*Enterococcus faecalis* VRE (ATCC 51575)

*Escherichia coli* O157:H7 (ATCC 35150)

*Staphylococcus aureus* MRSA (ATCC 33592)

**Malodor(s) (Activity)** – eliminates (destroys) odors and odor-causing bacteria on hard non-porous surfaces in restroom areas, behind and under sinks and counters, and storage areas (where bacterial growth can cause malodors).

{Note to reviewer: We will choose one or more of these statements depending on available space on the product label.}

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus.
- (This product or product name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against Influenza Type A<sub>2</sub> (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product has demonstrated effectiveness against Influenza Type A<sub>2</sub> (Hong Kong), (VR-544), and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus.

#### **(Emerging Pathogens Claims)**

(Oxivir Tb Wipes) (This product) meets the criteria to make claims against certain emerging viral pathogens from the following viral category:

- Enveloped Viruses
- Large, Non-Enveloped Viruses
- Small, Non-Enveloped Viruses



(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer. Changes from previous approved label are highlighted in yellow.)

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped Viruses	<b>One</b> of the following: Feline Calicivirus (ATCC VR-782) / Norovirus Poliovirus Type 1 (ATCC VR-1562) Rhinovirus Type 14 (ATCC VR-284) Rhinovirus Type 37 (ATCC VR-1147) Adenovirus Type 8 (ATCC VR-1368) Rotavirus, Strain WA
Large, Non-Enveloped Viruses	<b>One</b> of the following: Feline Calicivirus (ATCC VR-782) / Norovirus Poliovirus Type 1 (ATCC VR-1562) Rhinovirus Type 14 (ATCC VR-284) Rhinovirus Type 37 (ATCC VR-1147)
Small, Non-Enveloped Viruses	<b>Two</b> of the following: Feline Calicivirus (ATCC VR-782) / Norovirus Poliovirus Type 1 (ATCC VR-1562) Rhinovirus Type 14 (ATCC VR-284) Rhinovirus Type 37 (ATCC VR-1147)

(Oxivir Tb Wipes) (This product) has demonstrated effectiveness against viruses similar to *[insert name of emerging virus]* on hard, non-porous surfaces. Therefore, Oxivir Tb Wipes can be used against *[insert name of emerging virus]* when used in accordance with the directions for use against *[insert name of supporting virus(es) from list above]* on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at *[insert pathogen-specific website address]* for additional information.

*[Insert name of illness / outbreak]* is caused by *[insert name of emerging virus]*. Oxivir Tb Wipes kills similar viruses and therefore can be used against *[insert name of emerging virus]* when used in accordance with the directions for use against *[insert name of supporting virus(es)]* on [hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

#### **DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Not for personal cleansing. This is not a baby wipe. Do not flush in toilet.

*{Note to reviewer: For labels that list semi-critical devices as defined by FDA.}*

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

#### **For Use as a (One-Step) (Cleaner)/(Disinfectant):**

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.



(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer. Changes from previous approved label are highlighted in yellow.)

3. All surfaces must remain visibly wet for 1 minute. Use a 5 minute contact time for Tuberculosis. Use a 10 minute contact time for fungi.
4. Allow to air dry (or rinse (with potable water if necessary)).

Note: All food contact surfaces must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

**For Use as (Daily) (Bathroom) (Restroom) (Shower Rooms) (Locker Rooms) (Athletic Equipment) (OneStep) Cleaner/Disinfectant:**

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
3. To disinfect, all surfaces must remain wet for one (1) minute. Use a 5 minute contact time for Tuberculosis. Use a 10 minute contact time for fungi.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

**KILLS HIV AND HCV and HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS**

**PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings (Hospitals, Nursing Homes) and other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING AGAINST HIV-1 (AIDS Virus), HBV OR HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

**Cleaning Procedures:** Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of this product.

**Contact Time:** Allow surface to remain wet for 1 minute to kill HIV-1, HBV and HCV. Use a 5 minute contact time for Tuberculosis and a 10 minute contact for fungi.

**Disposal of Infectious Material:** Blood/body fluids must be autoclaved and disposed according to Federal, State and local regulations for infectious waste disposal.

**For Use as a Tuberculocide:**

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 5 minutes. Use additional towelettes if needed to ensure the correct wet contact time.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change towelette after each use (application).

**To Kill Fungi:**

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
3. All surfaces must remain visibly wet for 10 minutes. Use additional towelettes if needed to ensure the correct wet contact time.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

**For use as a Non-Food Contact Sanitizer:**

1. Pre-clean heavily soiled areas.
2. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
3. Allow the surface to remain wet for 30 seconds.
4. Wipe surfaces dry (or rinse) (or allow to air dry).

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5. Change towelette after each use (application).

**For Use as a Cleaner and/or Deodorizer:**

Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces. Allow to air dry (or rinse (with potable water if necessary)).

**Animal Housing Facilities (Including Veterinary Clinics, (Equine) Farms, Livestock, Swine and Poultry Houses):  
For cleaning and disinfecting the following hard, non-porous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.**

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding or watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Pull towelette from dispenser (canister) and wipe hard, non-porous environmental surfaces.
5. All surfaces must remain visibly wet for 1 minute.
6. Allow to air dry (or rinse (with potable water if necessary)).
7. Ventilate buildings and other closed spaces.
8. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

NOTE: Not for use on handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.

***(Package Opening Instructions :)***

***(Rigid Can with EZ-Open Lid)***

Dispenser Directions: Do Not Remove Lid. Lift Lid to expose dispenser and seal film. Using finger, push through film at vent hole and remove film. Pull wipe up from center of roll and pull towards you to insert in single wipe dispenser. Simply pull wipe at angle towards you to dispense one wipe at a time. To dispense multiple wipes, pull wipe away from you, out of single wipe dispenser and pull up. Separate wipe at perforation. When finished, close lid to retain moisture.

To Open New Package: No Need to Remove Lid. Lift lid to expose dispenser and seal film, which covers wipe roll. Simply puncture and tear film at the vent holes and remove film from canister.

To Open Package: Open lid/flap and pull out wipe at an angle from center of roll. When finished, close lid to retain moisture.

***(Rigid Can with Traditional-Open Lid)***

Dispenser Directions: Remove lid to expose dispenser and seal film. Remove film. Pull wipe up from center of roll and thread through lid. Replace lid. Pull wipe at angle towards you to dispense one wipe at a time. Separate wipe at perforation. When finished, close lid to retain moisture.

To Open New Package: Remove lid to expose dispenser and seal film, which covers wipe roll. Remove film. Thread wipe through lid. Replace lid.

To Open Package: Open lid/flap and pull out wipe at an angle from center of roll. When finished, close lid to retain moisture.

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer. Changes from previous approved label are highlighted in yellow.)

### **(Stand Up Pouch)**

Dispenser Directions: Remove film seal from wipe access port. Pull first wipe from center of roll. Insert first wipe in to easy thread dispenser. Insert easy thread dispenser into port and make a 1/4 turn clockwise to lock in place. Pull wipes at an angle to dispense. Dispense as many as required for job and break off at perforation. After use, store next wipe in easy thread dispenser cavity and snap lid closed to retain moisture.

To Open New Package: Remove film seal (from orifice) (over/from cap). Twist dispenser counterclockwise and remove to access wipe roll. Grab first wipe from center of roll. Insert wipe in dispenser orifice. Insert dispenser, twist clockwise until it locks.

To Open Package: Open lid/flap and pull out wipe at an angle from center of roll. When finished, close (click) (snap) lid/flap (closed) to retain moisture.

### **(FlatPack)**

[For re-sealable flatpack, transport pack or softpack, flexible package:]

[To Open Package:]

1. Open [click-lock] [closure] and peel back [or] [remove] seal.
2. Pull out [one] wipe [sheet] [at a time][, use as directed].
3. [When finished,] [firmly] close [click-lock] [closure] to retain moisture [to prevent drying between uses].

### **(Re-sealable soft pack:)**

1. Remove the seal (from the place shown on the label).
2. Remove one sheet at a time.
3. Close the seal (to prevent drying between uses).

### **STORAGE AND DISPOSAL:**

Do not contaminate water, food or feed by storage or disposal.

#### **Pesticide Disposal:**

Store in original container in areas inaccessible to small children. Keep securely closed.

#### **Container Disposal:**

**NONREFILLABLE READY-TO-USE FORMULATIONS:** *Note to reviewer: The following text will be used on nonrefillable RTU container labels:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash(, or offer for recycling if available).

**REFILLABLE CONTAINERS:** *Note to reviewer: The following paragraph will be used on labels for refillable containers:*

Refillable container. Refill this container with [insert one of the following brand names: Oxivir Wipes, Oxivir Tb Wipes] only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

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(Note to reviewer: *One of the following statements will be used, depending on the type of container*)

*(For product supplied in refillable or non-refillable containers)*

**Towelette Storage/Disposal:** Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Tightly close lid between uses to retain moisture.

*(For product supplied in resealable packages:)*

**Towelette Storage/Disposal:** Dispose of (wipe) (towelette) (cloth) in trash after use. Do not flush. Reseal container label between uses to retain moisture.

**ENVIRONMENTAL HAZARDS** *(for labels with veterinary use patterns)*

This product is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk.

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Optional Graphics:

(Note to Agency: Text appearing in parenthesis is done to show optional text which can be used partially or in its entirety. Commas may be added where needed. Text in brackets is a note to the Reviewer. Changes from previous approved label are highlighted in yellow.)



(Do not flush symbol from INDA)



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## **OXIVIR™ WIPES REFERENCE SHEET**

*(Insert verbatim any Claims statements from the Claims sections from above.)*

### **DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

*(Insert verbatim any set(s) of Directions For Use from above)*

See the container label for use directions and additional required information for First Aid, Precautionary Statements, and Storage and Disposal.

EPA Reg. No. 70627-60

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